FUSION- vitamin c, ferrous fumarate, polysaccharide iron complex, lactobacillus casei (ke-99) capsule

**US Pharmaceutical Corporation** 

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**FUSION**<sup>TM</sup>

Supplement Facts			
Serving Size: 1 Capsule			
			% Daily Value
			for Pregnant or
Amount Per Serving		%DV*	Lactating Women
Vitamin C	25 mg	42%	42%
Iron	130 mg	g 722%	722%
(65 mg from Ferrous Fumarate)			
(65 mg from Polysaccharide Iron Complex)			
Lactobacillus casei (KE-99)	20 ma	+	+
200 Billion CFU/g**	30 mg	1	1
* Percent daily value based on 2,000 calorie intake for adults			
and children 12 years and older. † Daily value not established			
** Colony Forming Units per gram (CFU/g) at time of manufacturing	1		

Other Ingredients: Titanium Dioxide, FD&C Blue #1, FD&C Red # 40, Hypromellose,

Microcrystalline Cellulose, Magnesium Stearate.

Patent Numbers: USA:6,797,266; 5,626,883; Mexico MX/a/2008/004461; Singapore: 200802623-9 and other countries.

**INDICATIONS:** Fusion<sup>TM</sup> is indicated for the treatment of iron deficiency anemia, which may occur due to an increased need for iron, a deficient intake of iron, or an excessive loss of iron. Also for treatment of condition in which iron deficiency and vitamin C deficiency occur together.

**CONTRAINDICATIONS:** Fusion  $^{TM}$  is contraindicated in patients with a known hypersensitivity to any of its ingredients; also, all iron compounds are contraindicated in patients with hemosiderosis, hemochromatosis, or hemolytic anemias.

**Ferrous Fumarate and Polys accharide Iron Complex:** All Fusion<sup>TM</sup> products include a unique patented source of iron, e.g. Ferrous Fumarate and Polysaccharide Iron Complex (U.S. Patent No: 11/243,043 Pending). "An increase in tolerability is observed with the (patented formulation) and is believed to occur as the result of distributing the total iron content in the composition among compounds that provide iron to the patient's blood stream via two different mechanisms. The ferrous salts are readily absorbed in the upper gut, by direct dissolution and absorption of the ferrous iron by the bloodstream. However, the iron available from PIC is absorbed in the lower gut, via an active protein transport mechanism".

Clinical Studies: Picinni, L.-Ricciotti, M. 1982. Therapeutic effectiveness of an iron-polysaccharide complex in comparison with iron fumarate in the treatment of iron deficiency anemias: PANMINERVA MEDICA-EUROPA MEDICA, Vol. 24, No.3, pp. 213-220 (July-September 1982).

**PRECAUTIONS:** The use of this product by immunocompromised patients or treatment of any disorder must be medically supervised by a physician.

**OVERDOSE:** Iron: Signs and Symptoms: Iron is toxic. Acute overdosage of iron may cause nausea,

vomiting, and, in severe cases, cardiovascular collapse and death. Other symptoms may include pallor and cyanosis, melena, shock, drowsiness and coma. The estimated overdose of orally ingested iron is 300-mg/Kg body weight. When overdoses are ingested by children, severe reactions including fatalities, have resulted. Fusion<sup>TM</sup> should be stored beyond the reach of children to prevent against accidental iron poisoning. Keep this product and all drugs out of reach of children.

**DOSAGE AND ADMINISTRATION:** Adults (persons over 12 years of age), one (1) capsule daily, between meals, or as prescribed by a physician. Do not exceed recommended dosage. Do not administer to children under the age of 12.

**HOW SUPPLIED:** Fusion<sup>TM</sup> are Maroon Opaque Vcaps<sup>®</sup> Plus capsules imprinted "US" logo and "F" in white. Child resistant bottles of 30 capsules, NDC# 52747-501-30. Dispense in a tight, light-resistant container as defined in the USP/NF with a child resistant closure. Vcaps<sup>®</sup> Plus and the Vcaps<sup>®</sup> Logo are trademarks used under license.

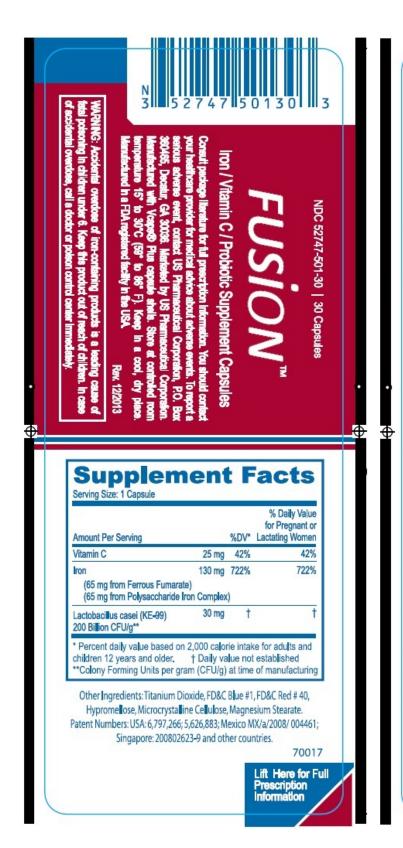
Consult package literature for full prescription information. You should contact you healthcare provider for medical advice about adverse events. To report a serious adverse event, contact US Pharmaceutical Corporation, P.O. Box 360465, Decatur, GA 30036. Marketed by US Pharmaceutical Corporation. Manufactured with Vcaps® Plus capsule shells. Manufactured in a FDA registered facility in the USA.

**WARNING:** Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

Store at controlled room temperature 15° to 30°C (59° to 86° F). Keep in a cool, dry place.

Iron / Vitamin C / Probiotic Supplement Capsules

**Packaging** 



## NDC 52747-501-30 **Fusion**<sup>TM</sup>

IRON / VITAMIN C /

## PROBIOTIC SUPPLEMENT CAPSULES

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HOW SUPPLIED: Fusion™ are Maroon Opaque Vcaps® Plus capsules imprinted "US" logo and "F" in white. Child resistant bottles of 30 capsules, NDC# 52747-501-30. Dispense in a tight, light-resistant container as defined in the USP/NF with a child resistant closure. Store at controlled room temperature 15° to 30°C (59° to 86° F). Keep in a cool, dry place. Vcaps® Plus and the Vcaps® Logo are trademarks used under license.

Rev. 12/2013

## **FUSION**

vitamin c, ferrous fumarate, polysaccharide iron complex, lactobacillus casei (ke-99) capsule

Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:52747-501
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	25 mg	
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW895810WR)	FERROUS CATION	65 mg	
IRON POLYMALTOSE (UNII: UM5219H89V) (FERRIC CATION - UNII:91O4LML611)	FERRIC CATION	65 mg	
LACTOBACILLUS CASEI (UNII: SA940P2U00) (LACTOBACILLUS CASEI-UNII:SA940P2U00)	LACTOBACILLUS CASEI	30 mg	

Inactive Ingredients				
Ingredient Name	Strength			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
HYPROMELLOSES (UNII: 3NXW29 V3WO)				
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)				
MAGNESIUM STEARATE (UNII: 70097M6130)				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:52747-501-30	30 in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
dietary supplement		12/30/2014		

Supplement Facts				
Serving Size:		Serving per Container :		
A	Amount Per Serving	% Daily Value		
color				
shape				
size (solid drugs)	19 mm			
scoring	1			
imprint				

## Labeler - US Pharmaceutical Corporation (048318224)

Establishment			
Name	Address	ID/FEI	Business Operations
Altora Pharma Solutions		044404586	manufacture (52747-501)

Revised: 12/2015 US Pharmaceutical Corporation